# Therapeutic Goods (Adverse Event Management System—Sponsors) (Arrangement for Computer Programs) Instrument 2023

I, Nicholas Henderson, as delegate of the Secretary of the Department of Health and Aged Care, make the following instrument.

Date 5 May 2023

Nicholas Henderson
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

# Contents

## 1 Name

This instrument is the *Therapeutic Goods (Adverse Event Management System—Sponsors) (Arrangement for Computer Programs) Instrument 2023*.

## 2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| **Commencement information** | | |
|---|---|---|
| **Column 1** | **Column 2** | **Column 3** |
| **Provisions** | **Commencement** | **Date/Details** |
| 1. The whole of this instrument | 12 May 2023. | 12 May 2023 |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under subsection 7C(1) of the *Therapeutic Goods Act 1989*.

## 4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) biological;
(b) medicine;
(c) Secretary;
(d) sponsor.

In this instrument:

***Act*** means the *Therapeutic Goods Act 1989*.

***adverse event*** means an adverse event that occurs in relation to a person in Australia following the administration of a medicine or biological.

Note: An adverse event may not necessarily have a causal relationship with the administration of the medicine or biological.

***AEMS*** means the Adverse Event Management System maintained by the Therapeutic Goods Administration.

***Therapeutic Goods Administration***, or ***TGA,*** means the part of the Department known as the Therapeutic Goods Administration.

***therapeutic goods information*** has the meaning given by subsection 61(1) of the Act.

## 5 Arrangement for use of computer programs to make decisions

For subsection 7C(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the use of the computer program mentioned in column 2, is arranged for the purposes mentioned in column 3.

# Schedule 1—Arrangement for computer programs

Note: See section 5.

| Arrangement for use of computer programs to make decisions | | |
|---|---|---|
| **Column 1** | **Column 2** | **Column 3** |
| **Item** | **Computer program** | **Purposes** |
| 1 | AEMS | any purposes in relation to the making of decisions, under subsection 61(5AA) of the Act, to release to sponsors therapeutic goods information of the kind specified in an instrument made under subsection 61(5AB) relating to the AEMS |

Note 1: At commencement, the instrument made under subsection 61(5AB) relating to the AEMS is the *Therapeutic Goods (Adverse Event Management System—Sponsors) (Information) Specification 2023*, which is a legislative instrument that may be accessed at www.legislation.gov.au.

Note 2: Under subsection 61(5AA) of the Act, the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.